



THE
COLLEGE
OF
PHYSICIANS
AND
SURGEONS
OF
ONTARIO

May 27, 2016

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Dear Mr. Moleschi,

**Re: Consultation Feedback on Proposed Changes to the *Pharmacy Act* Regulations
(Administration of Vaccines by Pharmacists)**

Thank you for requesting the College of Physicians and Surgeons of Ontario's (CPSO) feedback on the Ontario College of Pharmacists' (OCP) proposed amendments to the *Pharmacy Act, 1991* Regulations. The CPSO appreciates the invitation to participate in the OCP's consultation.

The CPSO values initiatives that ensure patient access to care and is generally supportive of the proposed regulation amendments. We do however, have two key concerns. We also raise a few additional points for the purpose of providing constructive feedback as the OCP finalizes its proposed regulation amendment.

I. Key Concerns

Vaccines for Patients under 18

The CPSO notes that the OCP's proposed regulation amendments list thirteen specific vaccinations that pharmacists, pharmacy students and interns would administer. It is unclear from the consultation materials what rationale has informed the selection of these vaccines. Some of the listed vaccines require a prescription prior to administration and some do not. Two implications, associated with the health protection and promotion of young patients, arise from the proposed regulations.

First, we would note that when young patients see their primary care provider for vaccinations, these visits afford primary care providers important opportunities to evaluate the general health, development and growth of the young patient and provide counseling for the purposes of health promotion. Should younger patients receive vaccinations from pharmacists, the opportunity for ongoing health monitoring and health promotion by the primary care provider will be lost. This is particularly a risk where patients attend a pharmacist for a vaccination that does not require a prescription. In most cases, vaccinations for children are available at the prescriber's clinic and there should not be a need for pharmacist administration in order to enhance access.



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Second, while some childhood vaccinations have been captured in the proposed regulation amendments, the majority of routine immunizations such as the Measles Mumps Rubella (MMR) vaccination have not. In addition, the types of vaccines used in young children (e.g. Monovalent Men C-C, adsorbed combination vaccines containing Haemophilus Influenzae Type B (HiB)) are different from those used in older children and adults. The type of vaccine indicated for a child may vary if the child has an immune or hematologic condition. The lack of comprehensiveness of the vaccines pharmacists can administer and the differing indications may give rise to confusion amongst patients and their caregivers, and could result in some patients not receiving standard vaccinations. For instance, the parents of children who receive some 'routine' vaccinations from pharmacists may incorrectly form the opinion that they have received all necessary vaccinations from the pharmacist, not realizing that standard and important vaccinations such as the MMR have not and cannot be provided by the pharmacist.

For these reasons, the CPSO recommends that vaccination of minors (patients under 18) not be included in the proposed regulation amendments, but that those patients continue to receive vaccinations from their primary care providers.

Non-Prescription Vaccinations

We note that the proposed regulation amendments would enable pharmacists to provide specific non-prescription vaccinations to patients: pneumococcal, meningitis, and HiB.

Since these are non-prescription, patients can come to pharmacists directly to receive these vaccinations, without having a clinical assessment from a primary care provider. The CPSO notes that administration of both pneumococcal and meningitis is fairly straightforward, with pneumococcal being routine at age 65 and meningitis being administered for young adults who weren't vaccinated in adolescence. HiB is however not straightforward. This vaccination is never routine for adults, and would only be given to certain high risk groups. It is unclear from the proposed regulations how vaccinations for HiB will be managed by pharmacists, and specifically, absent a clinical assessment, how pharmacists will determine whether a patient is a candidate for HiB.

To ensure patient safety, the CPSO recommends that HiB (Haemophilus Influenzae Type B) be excluded from the proposed regulation amendments.

II. Constructive Comments

In analyzing the proposed regulation amendments, the CPSO noted a few additional issues that we raise for the purposes of seeking clarity and providing constructive feedback.

a) Clinical Assessments

The CPSO notes that for some of the listed vaccinations, a clinical assessment would be required prior to administration, for the purpose of determining suitability of the vaccination for the patient, and to explore any potential contraindications. It would be helpful if the OCP could clarify and make explicit that pharmacists will not be conducting these types of clinical assessments (which appear to be outside of pharmacists' knowledge, skill and judgment) but rather that pharmacists will be administering the vaccinations after a clinical assessment has been conducted by a patient's primary care provider.

b) Education and Training

The proposed regulation amendments will allow pharmacy students and interns to administer vaccinations under the supervision of a duly trained and registered pharmacist. The CPSO is supportive of this but recommends that the OCP pursue opportunities to formalize training among pharmacy students and interns. Ideally, pharmacy students and interns in Ontario would receive formal training commensurate to that of registered pharmacists under Health Canada's [Immunization Competencies for Health Professionals](#).

c) Documentation and Continuity of Care

Sharing of pertinent medical information is essential to patient care and to ensure continuity of care. This is particularly the case in terms of vaccinations to ensure there is an accurate record of the immunizations provided and that any follow up courses or 'boosters' can be administered when required. Accordingly, the CPSO strongly recommends that as a companion to the proposed regulation amendments, the OCP develop expectations for pharmacists with respect to record keeping, and with respect to sharing information with the patient's primary care provider.

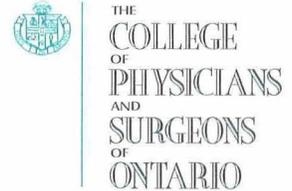
d) Conflicts of Interest

We note that the proposed regulation amendments will enable pharmacists to both dispense and administer vaccines to patients. This has the potential to give rise to conflicts of interest. We trust the OCP has relevant guidance in place regarding potential conflicts of interest and would encourage the OCP to ensure all members who may provide vaccinations under the proposed regulation amendments are familiar with that guidance.

e) Communication with the Public

Consistent with the comments provided above regarding patients under 18, the CPSO notes that not all the vaccinations listed in the proposed regulation amendments are comprehensive even for adult patients. It will be essential for patients to understand that pharmacists can only

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provide specific types of vaccinations and that in order to ensure that all routine or otherwise clinically indicated vaccinations can be obtained, patients must always consult their primary care provider. Accordingly, the CPSO believes it important that any pharmacist providing vaccinations make it clear to patients that the vaccinations offered are not comprehensive.

We hope that you find these comments helpful as you move forward in regulation and standards development. If you have any questions about the comments provided, please do not hesitate to contact me.

Yours very truly,

A handwritten signature in black ink that reads "Rocco Gerace". The signature is written in a cursive, flowing style.

Rocco Gerace MD
Registrar